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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/823,203	04/13/2004	Que Lan	054030-0056	5029
31096	7590	08/23/2005	EXAMINER	
GODFREY & KAHN, S.C. 780 N. WATER STREET MILWAUKEE, WI 53202			ROBINSON, HOPE A	
			ART UNIT	PAPER NUMBER

1656

DATE MAILED: 08/23/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

10/823,203

Applicant(s)

LAN ET AL.

Examiner

Hope A. Robinson

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 09 June 2005.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-11 is/are pending in the application.
- 4a) Of the above claim(s) 1-7 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 8-11 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 6/9/05 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

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***Application Status***

1. The Art Unit location of your application in the USPTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Art Unit 1656.
2. Applicant's response to the Office Action mailed March 11, 2005 on June 9, 2005, is acknowledged.

***Claim Disposition***

3. Claims 8-10 have been amended. Claims 1-11 are pending. Claims 8-11 are under examination.

***Drawing***

4. The drawing filed on June 9, 2005 is objected to because Figure 2 has several sequences, however, the top panel is not identified by the corresponding SEQ ID NO:, unlike the bottom panel which are identified by the appropriate sequence identifiers. It appears that the sequences listed do not all correspond to the SEQ ID NOS listed in the bottom panel. Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for

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consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance. Applicant is reminded to file Formal Drawings.

***Withdraw-Sequence Compliance***

5. Previous objection to the specification are withdrawn by virtue of submission of an amendment.

***Withdrawn-Specification Objections***

6. Previous objection to the specification are withdrawn by virtue of submission of an amendment.

***Withdrawn-Objection to Claims***

7. Previous objection to claims are withdrawn by virtue of submission of an amendment to the claims.

***Withdrawn-Claim Rejections - 35 USC § 112***

8. Previous rejection to claims under 35 U.S. C. 112, first paragraph written description is withdrawn by virtue of submission of an amendment.

***New-Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

9. Claims 8-11 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the protein set forth in SEQ ID NO: 3, does not reasonably provide enablement for the full scope of the claims. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make the invention commensurate in scope with these claims. The enablement requirement refers to the requirement that the specification describe how to make and how to use the invention. There are many factors to be considered when determining whether there is sufficient evidence to support a determination that a disclosure does not satisfy the enablement requirement and whether any necessary experimentation is undue. These factors include, but are not limited to: Quantity of Experimentation Necessary; Amount of direction or guidance presented; Presence or absence of working examples; Nature of the Invention; State of the prior art and Relative skill of those in the art; Predictability or unpredictability of the art and Breadth of the claims (see *In re Wands*, 858 F.2d at 737, 8 USPQ2d at 1404 (Fed. Cir. 1988)). The factors most relevant to the instant invention are discussed below.

The amount of experimentation required to practice the claimed invention is undue as the claims do not set forth what biological activity of the claimed protein (AeSCP-2) is altered to be able to measure the specific activity in an assay to detect an agonist or antagonist, to enable an artisan to practice the claimed invention

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commensurate in scope with the claims. The art recognizes that the sterol carrier protein-2 family (SCP-2) has the following activities: 1) mediate cholesterol trafficking and metabolism, 2) bind cholesterol with high affinity, 3) intracellular transportation of cholesterol, 4) bind fatty acid and fatty acyl coA, 5) important component of steroid biosynthesis, 6) accelerate conversion of cholesterol to steroids in mitochondria and 7) enhance sterol cycling between microsome and plasma membrane (see Murphy et al., Journal of Lipid Research, vol. 41, pages 788-796, 2000). The homology of AeSCP-2 to SCP-2 is disclosed as 69% and there is no clear indication that AeSCP-2 has parallel function as SCP-2 (see Krebs et al. Insect Molecular Biology, vol. 12, no. 1, pages 51-60, 2003), therefore, the instant claims and specification needs to provide sufficient information regarding the activity to be altered in the claims. Therefore a large quantity of experimentation is necessary to generate biological targets that interact with AeSCP-2 in the presence of a test compound and determine if the compound is an agonist or antagonist based on inhibition or enhancement of AeSCP-2 activity absent guidance as to the specific activity being measured and the biological target. Thus, this is merely an invitation to the skilled artisan to use the current invention as a starting point for further experimentation.

The art recognizes that the SCP-2 protein family has several activities and it is unclear whether or not AeSCP-2 has the same activities, thus, the claimed method to identify a compound that alters the biological activity of AeSCP-2 is unpredictable. Predictability of which potential changes can be tolerated by the protein or what compound will affect the biological activity of the claimed protein, or the activities identified in the art for the SCP-2 protein, if in fact the SCP-2 and AeSCP-2 have parallel

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functions, requires a knowledge of and guidance with regard to which activity is targeted and the class of compounds being used. For example, to go through the entire Merck catalog of compounds searching for one that will either inhibit or enhance a protein for which a specific activity has not been flattened by science, is not routine experimentation or predictable. In this case, the necessary guidance has not been provided in the specification.

The state of the prior art provides evidence for the high degree of unpredictability as stated above. Further, Krebs et al. (Insect Molecular Biology, vol. 12, no. 1, pages 51-60, 2003) disclose that the AeSCP-2 protein is 69% homologous to SCP-2, however, states that it is unclear whether the AeSCP-2 has parallel function as SCP-2 family members (page 52) which demonstrates the unpredictability of the biological activity.

The specification lacks adequate guidance/direction to enable a skilled artisan to practice the claimed invention commensurate in scope with the claims. The working examples provided do not rectify the missing information. Further, the nature and properties of this claim is difficult to ascertain from the examples provided as one of skill in the art would have to engage in undue experimentation to construct an assay to determine whether or not an activity of the claimed protein is affected.

The specification does not provide support for the broad scope of the claims. The issue in this case is the breath of the claims in light of the predictability of the art as determined by the number of working examples, the skill level artisan and the guidance presented in the instant specification and the prior art of record. This make and test position is inconsistent with the decisions of *In re Fisher*, 427 F.2d 833, 839, 166 USPQ 18, 24 (CCPA 1970) where it is stated that "...scope of claims must bear a reasonable

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correlation to scope of enablement provided by the specification to persons of ordinary skill in the art...". Without sufficient guidance, determination of having the desired biological characteristics is unpredictable and the experimentation left to those skilled in the art is unnecessarily and improperly extensive and undue. See *In re Wands*, 858 F.2d at 737, 8 USPQ2d at 1404 (Fed. Cir. 1988). Thus, for all these reasons, the specification is not considered to be enabling for one skilled in the art to make and use the claimed invention as the amount of experimentation required is undue, due to the broad scope of the claims, the lack of guidance and working examples provided in the specification and the high degree of unpredictability as evidenced by the state of the prior art. Therefore, applicants have not provided sufficient guidance to enable one of skill in the art to make and use the claimed invention in a manner that reasonably correlates with the scope of the claims, to be considered enabling.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

10. Claims 8-11 are rejected under 35 U.S.C. 112, second paragraph, as failing to set forth the subject matter, which applicant (s) regard as their invention.

Claim 8 and the dependent claims hereto are indefinite for the recitation of "biological activity" because it is unclear what activity is to be measured in the method, considering the art recognizes that a family of proteins that are similar to the subject protein has at least 7 different activities.



***Withdrawn-Claim Rejections - 35 USC § 102***

11. The rejection of record has been withdrawn based on applicant's statements that this Krebs et al. reference is applicant's own work and does not qualify as prior art under 35 U.S.C. 102(a).

***Response to Arguments***

12. The response filed on June 9, 2005 has been considered. Note that the rejections of record have been withdrawn based on amendments made to the claims or arguments presented. However, new rejections have been instituted under 35 U.S.C. 112, first and second paragraphs for the reasons stated above.

***Conclusion***

13. No claims presently allowable.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Hope A. Robinson whose telephone number is 571-272-0957. The examiner can normally be reached on Monday-Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kathleen Kerr, can be reached at (571) 272-0931. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Hope Robinson, MS

Patent Examiner

**HOPE ROBINSON**  
**PATENT EXAMINER**

8/18/05